UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 99-CV-2496 (GK)
	)	
PHILIP MORRIS USA INC.	)	Next scheduled appearance:
PHILIP MORRIS INC., et al.,	)	Trial (ongoing)
	)	
Defendants.	)	

WRITTEN DIRECT EXAMINATION OF

MICHAEL WAYNE OGDEN

SUBMITTED PURSUANT TO ORDER #471A

Q: Please state your name.

A: Michael Wayne Ogden.

Q: Where are you employed?

A: I am employed by R.J. Reynolds Tobacco Company ("Reynolds").

Q: What are your current titles or positions?

A: I am the Director of the Human Studies Division in Reynolds' Research and Development Department and am a Principal Scientist.

Q: Before you describe your work at Reynolds, let's explore your professional background starting with your post-secondary educational background?

A: I earned a B.S. from Emory and Henry College in 1980 with dual majors in Chemistry and Applied Mathematics. I earned a Ph.D. in Analytical Chemistry from Virginia Polytechnic Institute and State University, commonly referred to as Virginia Tech, in 1985.

Q: While you were obtaining your Ph.D., did you teach?

A: Yes. I was a teaching assistant for Professor Harold McNair at Virginia Tech, assisting him with chromatography courses sponsored by the American Chemical Society that he taught to outside chemists from industry, academia, and government. After serving as a teaching assistant for Dr. McNair, I taught several of these courses on my own. Among the government employees I taught were chemists from the FDA responsible for drug evaluations, as well as chemists from the FBI responsible for crime scene investigations (e.g., air samples from an arson investigation or ink analysis).

Q: Have you done any teaching or mentoring since obtaining your Ph.D.?

A: Yes. I was a Visiting Professor of Chemistry and am an Adjunct Professor of Chemistry at Virginia Tech with mentoring responsibilities for a post-doctoral fellowship

program. Reynolds had funded post-doctoral fellowships at The University of North Carolina, Wake Forest University School of Medicine, Duke University, and University of Rochester. In 1995, I began a new Reynolds post-doctoral fellowship program in analytical chemistry at Virginia Tech. To date, we've completed three post-doctoral fellows through the Virginia Tech Chemistry program and have three more fellows currently employed.

Q: Have you been an invited presenter at scientific conferences?

A: Yes, I was an invited presenter on ETS and ETS measurement issues at an international symposium on air quality issues in Poland and at a national meeting of ASHRAE (the American Society for Heating, Refrigerating and Air Conditioning Engineers). I also was an invited presenter on the use of capillary chromatography to assess environmental exposures at an American Chemical Society meeting.

Q: Have you served as a peer reviewer for scientific journals?

A: Yes. I've served as a peer reviewer for the major analytical chemistry journals, including *Analytical Chemistry*, the *Journal of Chromatography*, the *Journal of High Resolution Chromatography*, and the *Journal of Chromatographic Science*. I also have served as a peer reviewer for scientific journals focusing on environment-related issues, including *Environmental Science & Technology* and *Environment International*.

Q: Have you served on any editorial boards for peer-reviewed scientific journals?

A: Yes. I've served on the editorial boards of *Tobacco Science* and *Beiträge zur Tabakforschung International* (roughly translated, Contributions to Tobacco Research).

Q: Are you a member of any professional chemistry organizations?

A: Yes, I'm a member of the American Chemical Society, the Association of Official Analytical Chemists, and the American Society for Testing and Materials. I also serve as a representative to the International Organization for Standardization.

Q: You said your Ph.D. is in analytical chemistry. Would you briefly describe the general focus of analytical chemistry?

A: Analytical chemistry, very generally, involves identifying and measuring concentrations of chemical substances in a given environment.

Q: Have you specialized in any particular area of analytical chemistry?

A: Yes, I have specialized in chromatography, which involves separating, identifying, and quantifying various substances in complex chemical mixtures. This specialty involves identifying chemicals that exist in very small quantities in real-world environments and analyzing and measuring complex mixtures that exist at very low levels. In particular, I have specialized in what are called high-resolution techniques that involve separating complex mixtures into their component parts and quantifying them.

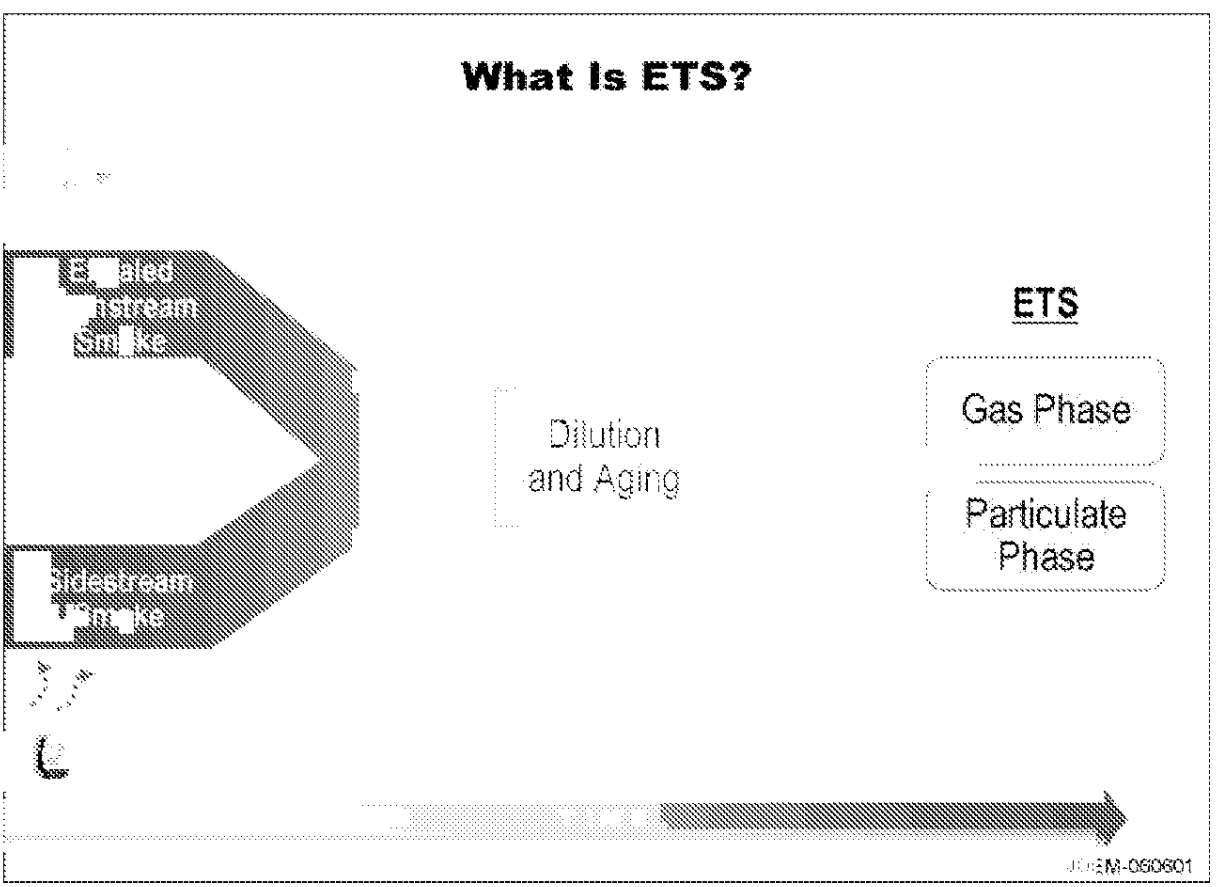
Q: Is your training in analytical chemistry and chromatography useful in research relating to ETS?

A: Yes.

Q: Why is that?

A: Primarily because ETS is so hard to accurately and reliably identify and measure. As depicted in very simplified form in JDEM-060601, ETS is a highly-complex, aged, and diluted mixture of (a) exhaled mainstream smoke -- the smoke exhaled by smokers; and (b) sidestream smoke -- the smoke that immediately comes off the lit end of the cigarette. It has a substantial number of constituents, many of which are present in extremely small quantities

measured in micrograms (millionths of a gram), nanograms (billionths of a gram), or picograms (trillionths of a gram) per cubic meter of air. ETS has two phases, a gas phase and a particulate phase, that exist in different ratios in ETS than they do in mainstream smoke. Over time, ETS (a) changes chemically as its component constituents interact among themselves and with other chemicals in the atmosphere; and (b) is rapidly diluted by ambient air. Further, ETS does not exist in a vacuum in the real world and, instead, exists in indoor environments that contain many chemicals and constituents from sources other than ETS. All of these factors about ETS make it particularly challenging for analysis and examination by analytical chemists, but well suited for, in particular, high-resolution chromatography, which permits identifying and measuring substances present at extremely low levels.



Q: Let's turn to your career at Reynolds. Would you briefly trace the positions you have held at Reynolds?

A: Certainly, but first I should explain that Reynolds' scientists may advance along one or both of two different internal "ladders" or career paths: a "technical ladder" that is solely for scientists in the Research and Development Department and the traditional, company-wide "management ladder." Reynolds hired me in 1985 as an R&D Chemist, an entry-level position for a Ph.D. scientist. I was promoted (a) to Senior R&D Chemist in 1988; (b) to Senior Staff R&D Chemist in 1991; (c) to Master Scientist in 1993; and (d) to Principal Scientist in 1998. The final two positions, Master Scientist and Principal Scientist, were positions on the technical ladder. In 2001, I assumed a position on the management ladder as well, serving as the Director of the Biological Chemistry Division, which division was reorganized into the Human Studies Division in 2003.

Q: What does the Principal Scientist title signify at Reynolds?

A: Principal scientist is the second-highest position on the technical ladder. Very generally, it is a recognition of subject matter expertise, technical knowledge, and scientific contributions as measured by, for example, having significant publications in scientific journals and/or having been awarded patents.

Q: Have you published articles in scientific journals while employed in Reynolds' Research and Development Department?

A: Yes, over sixty articles.

Q: Have you been awarded any patents?

A: Yes, I have two patents on an air sampling system for measuring, among other things, ETS.

Q: Would you describe your responsibilities as the Director of the Human Studies Division?

A: Although I had supervised other scientists in my technical ladder positions of Master Scientist and Principal Scientist, I also worked with those scientists in the field and in the laboratory as a hands-on researcher. Since my promotion to Director on the management ladder in 2001, I perform less actual bench science and my primary responsibilities are managing other scientists and setting the direction of Reynolds' research within the division.

Q: Now I'd like to turn to Reynolds' ETS-related research. Very generally, when did that research begin and what was its focus?

A: Based on my review of Reynolds' research that was conducted before I arrived, Reynolds' ETS research effort began in the 1970s and became more formalized and organized in the mid-1980s at or about the time I was hired. In the most general sense, Reynolds' ETS-related research effort has focused on attempting to measure ETS and ETS exposures in real-world environments.

Q: Hadn't there been research measuring, analyzing, and characterizing mainstream smoke (smoke inhaled by smokers) and sidestream tobacco smoke (smoke from the lit end of the cigarette), as well as their constituents, published well before that?

A: Yes, well before the 1970s, scientists had identified and measured many constituents in mainstream smoke and sidestream tobacco smoke. And we and others were aware that, because sidestream smoke is created at lower temperatures, many constituents, including many carcinogens, are emitted in sidestream smoke in higher amounts than they are in mainstream smoke. The 1972 Surgeon General's Report, for example, discussed the

published results of a 1960 study showing that "sidestream cigarette smoke condensate may contain more than three times as much benzo(a)pyrene as mainstream smoke." (U.S. Exh. 60,597 at page 123).

Q: Then why did Reynolds' ETS research effort start so much later?

A: For at least two reasons. First, ETS, on the one hand, and mainstream smoke and sidestream tobacco smoke, on the other hand, are very different substances in ways that, in this context, are important.

Q: How does ETS differ from mainstream and sidestream smoke?

A: Constituents present in mainstream smoke or sidestream smoke, if present in ETS, are in concentrations that are much, much smaller. For example, the concentration of particles in mainstream smoke is roughly 500,000 times that in ETS. ETS also undergoes chemical changes over time as it ages in the ambient air, while mainstream smoke is inhaled and then exhaled comparatively quickly and does not have time to undergo such changes. As a result, ETS and its constituents as found in real-world environments are much, much harder to measure. The knowledge and technology required to make measurements of ETS and its constituents as they exist in real-world environments simply did not exist before the 1970s and, in many important respects, did not exist until the 1980s or 1990s.

Q: You said there were at least two reasons. What else were you referring to?

A: The other thing I was referring to was that, before the 1970s, ETS had been less of an issue in the scientific community, in the public health community, with our customers in terms of their product desires, and in terms of legislative and regulatory efforts to limit or prohibit public smoking. As that changed over time and as ETS and its possible health effects

emerged as an important issue, Reynolds began to plan, explore, and then conduct research to find out what real-world ETS levels and exposures were.

Q: Why was Reynolds interested in finding out what real-world ETS levels and exposures were?

A: Because it is a first principle that you need to know what exposures are before you can evaluate health effects. Very simply, we believed that assessing the health effects of ETS exposures required, as an initial matter, knowing what those exposures were.

Q: Were there calls for this type of research from the outside scientific community?

A: Certainly. For example, the 1979 Surgeon General's Report (U.S. Exh. 64,071) observed that "[a]ttention to involuntary smoking is of recent vintage, and only limited information regarding the health effects of such exposure upon the nonsmoker is available. Therefore, research is needed to define these effects." (U.S. Exh. 64,071 at page 11-35).

Q: Did calls for this type of research continue into the early 1980s?

A: Yes. The 1982 Surgeon General's Report observed that, "the exposure of nonsmokers [to ETS] is more difficult to quantitate than that of the smoker" and that "many factors complicate the theoretical extrapolation of machine measurements of smoke constituents to the biologic effects to be expected with exposure of nonsmokers." (U.S. Exh. 60,598 at 239, 240). Specifically, it noted measurement difficulties created by (a) "dilution of constituents" in ETS (at 239); (b) the facts that the concentration of ETS "is dependent upon the amount of smoke generated, the volume of ambient air, and the type and amount of the ventilation of that space" (at 239-40); (c) the fact that "the chemical composition of [ETS] smoke changes with the passage of time" (at 240); and (d) the fact that ETS is a "continuous low-dose

exposure," rather than the "intermittent high-dose exposure" that occurs with mainstream smoke (at 240).

Q: Did any new types of evidence relating to ETS and disease causation emerge in the early 1980s?

A: Yes. Epidemiological studies relating to ETS first were published in the early 1980s and typically used marriage to a smoker as a proxy for exposure. The 1982 Surgeon General's Report noted the limitations this placed on interpreting the results of those studies because "[t]his estimate of exposure is subject to misclassification, as the nonsmoker may be a former smoker," and "the smoking habits of the current spouse may not approximate the actual exposure." (U.S. Exh. 60,598 at 243).

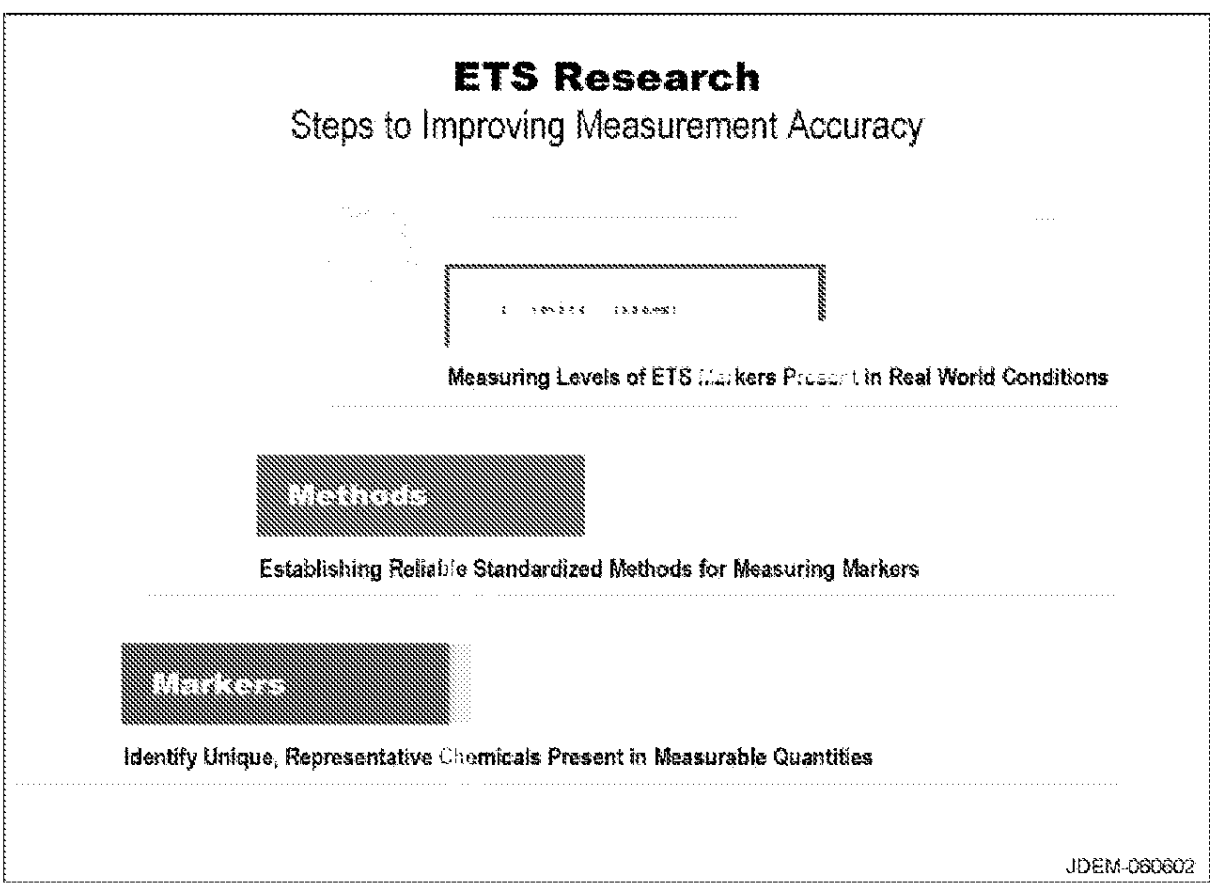
Q: Were these problems relating to measuring ETS levels and exposure resolved by 1986 when the 1986 Surgeon General's Report (JE-063709) and the National Research Council's 1986 report "Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects" (U.S. Exh. 63,708) reviewed the available scientific literature and concluded that ETS caused lung cancer?

A: No. To the contrary, the National Research Council's 1986 report (the "1986 NRC Report"), a copy of which is U.S. Exh. 63,708, noted several gaps in the then-existing state of scientific knowledge regarding ETS levels and exposures. It observed that "[a] suitable proxy or tracer air contaminant is not available for total ETS exposure" and that "the relative proportions of various constituents of ETS in the particulate and vapor phases need further study to determine the extent to which a tracer for one phase can be used to infer exposure to the other phase." (U.S. Exh. 63,708 at 96). It also stated that "[p]ersonal and

microenvironment monitoring studies should be conducted to determine the predictive value of various exposure assessment methodologies." (U.S. Exh. 63,708 at 97).

Q: Let's look at Reynolds' ETS-related research. What were the primary areas of focus for R.J. Reynolds ETS-related research?

A: They largely were what the 1986 NRC Report called for. Very generally, Reynolds' scientists researched ETS chemistry, ETS exposures, and ETS toxicology. Being a little more specific and as reflected in JDEM-060602, our research in the first two areas, ETS chemistry and exposures, focused on three sub-areas -- markers, methods, and measurement -- although not always in that order.



Q: What do you mean when you refer to ETS markers?

A: When I talk about markers, I am referring to our initial efforts to identify chemical constituents in ETS that were representative and present in quantities that could actually be measured in real-world environments. Scientists often refer to individual chemicals in complex mixtures that are both unique and proportional to other constituents in the mixture as "markers." So, in our efforts to research markers, we were trying to develop an understanding of what markers may be good or bad or better than others for measuring ETS in real-world environments.

Q: You mentioned research relating to methods. What did that entail?

A: Taking the markers we had identified and trying to develop analytical methods for measuring them. In other words, once we studied some of these markers and did our homework on them, we said to ourselves, "let's go out and see if we can actually develop chemical methods of analysis that allow us to reliably determine their presence and concentration." And, once we developed those methods, we had them validated by standard-setting organizations so they would be publicly available for use by all scientists as uniform, standardized tests for the particular components.

Q: What about the third type of research you mentioned, measurements?

A: The third phase was to actually apply those methods of measuring ETS markers in the real world. So, when I refer to measurement, I am referring to our efforts to actually assess human exposures to ETS in real-world environments.

Q: Let's go back to the first item you mentioned, markers. What did Reynolds' scientists do in connection with markers?

A: As I mentioned earlier, we first had to identify ETS markers that we could measure at the very low concentrations at which ETS exists in the real world. We began by looking at

what was known about collecting and analyzing mainstream smoke and sidestream smoke, the main precursors of ETS. This effort reflected a simple logic: An understanding of how to collect and analyze mainstream and sidestream smoke was fundamental to an understanding of ETS.

Q: What did Reynolds do?

A: Initially, two Reynolds scientists, Drs. Dube and Green, reviewed prior research and prepared a paper entitled "Methods of Collection of Smoke for Analytical Purposes." It was published in 1982 in *Recent Advances in Tobacco Science: Formation, Analysis, and Composition of Tobacco Smoke*, and JD-060419 is a copy. It reviews and analyzes prior research regarding collecting mainstream and sidestream smoke for analytical purposes. That provided a beginning for our examination of ETS. Many government-funded review reports have cited this paper, including the 1986 Surgeon General's Report (JE-063709 at pages 125, 127), the 1986 NRC Report (U.S. Exh. 63,708 at 26-27), and the Environmental Protection Agency's 1992 Risk Assessment (U.S. Exh. 88,654 at 3-3, 3-4).

Q: Was the fact that Drs. Dube and Green were affiliated with Reynolds disclosed in the article?

A: Yes, on the very first page (JD-060419 at 42).

Q: What was the next step in Reynolds' ETS-related research effort?

A: In the mid-1980s, Reynolds began organizing the ETS Division within its Research and Development Department. Dr. Charles Green, a co-author of the article I just mentioned and a Ph.D. analytical chemist with 15 years of experience at Reynolds headed the division. By the second half of 1985, staffing was essentially complete. The division included approximately 20 scientists or technicians, including at least six Ph.D. chemists. The majority

of the Ph.D. chemists, including myself, were newly-recruited from academia and other industries. Reynolds provided the division with a fully-equipped laboratory, including what was, at that time, a state-of-the-art environmental chamber. Recognizing the potential significance of this chamber to other ETS researchers, Reynolds' scientists described the chamber at the 1986 annual meeting of the Air Pollution Control Association.

Q: Were the proceedings of that meeting published?

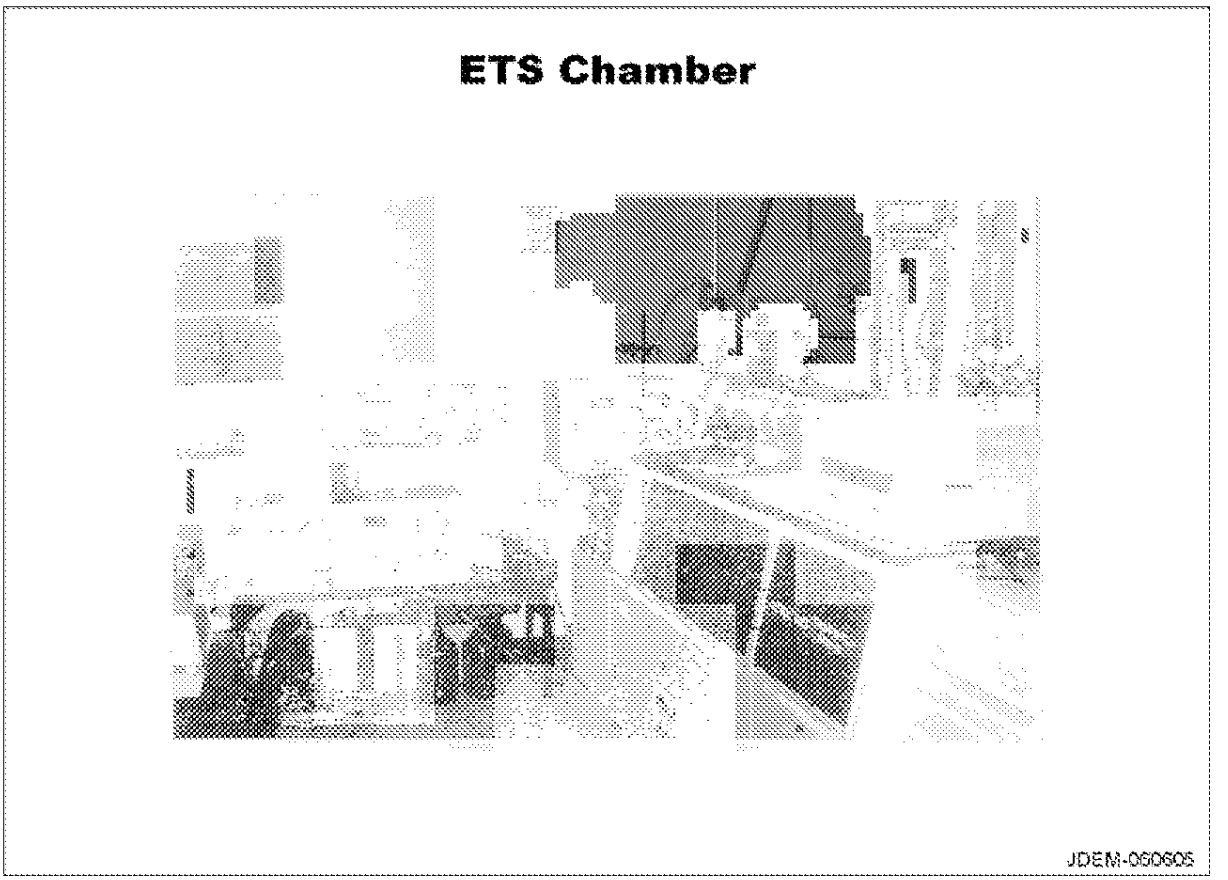
A: Yes. JD-064504 is the paper I was referring to and is entitled "A Test Chamber and Instrumentation for the Analysis of Selected Environmental Tobacco Smoke (ETS) Components." It was published in 1986 in the *Proceedings of the 79th Annual Meeting of the Air Pollution Control Association*.

Q: Does this presentation identify the authors' affiliation with Reynolds?

A: Yes, on the cover page.

Q: Please take a look at the photograph that is JDEM-060605. What does it show?

A: That is the instrumentation outside Reynolds' ETS chamber. The chamber was 18 cubic meters, which is roughly equivalent to a very large closet or a very small room measuring 8 feet wide, by 8 feet long, with a 7 1/2 foot high ceiling. It permitted us to generate true environmental tobacco smoke with actual smokers smoking. On the outside of this chamber and as shown in the picture, we installed sophisticated measurement equipment that allowed us to measure and study ETS in a way never before possible.



Q: How was the chamber used?

A: We began using this chamber to study ETS at or above concentrations that would be encountered in real-world environments.

Q: Why was there a need to build this ETS chamber given that there were pre-existing technologies available to measure and assess mainstream smoke and sidestream smoke?

A: As I mentioned previously, ETS is different from mainstream smoke and it is different from sidestream smoke. Unlike this room-sized chamber, the chambers used to study mainstream smoke and sidestream smoke typically are quite small and generally are little more than an enclosure around a cigarette. This environmental chamber allowed us to study

ETS in a much more realistic environment, particularly as it changed over time. It enabled us to identify chemical markers for ETS that could be measured at the levels that would be encountered by nonsmokers.

Q: How did Reynolds' scientists use the new ETS chamber?

A: In 1985, Reynolds equipped the chamber with instruments for investigating nicotine, a constituent of ETS that many scientists believed was a promising ETS marker. This led to our discovery in 1985 that nicotine in ETS is almost entirely in the gas phase. Prior to 1985, scientists had assumed that, as is the case with mainstream smoke and sidestream smoke, nicotine in ETS was attached to smoke particles and, therefore, was in the particulate phase of smoke. Until Reynolds discovered that, in ETS, nicotine exists in the gas phase, scientists had been looking in the wrong place for nicotine and were reporting scientifically invalid, unreliably low measurements of ETS nicotine.

Q: So scientists previously had been underestimating nicotine and, accordingly, had been underestimating ETS exposures when nicotine had been used as a marker for ETS?

A: Exactly. Prior to 1985, scientists were looking for ETS nicotine in the particle phase of ETS and presumably were not finding any or all of the nicotine in ETS's gas phase. Our discovery allowed scientists to find more nicotine in ETS, which eventually led to more accurate assessments of nicotine concentrations derived from ETS, and more accurate assessments of the amount of ETS present.

Q: Did Reynolds' scientists report this finding outside the company?

A: Yes. We presented the preliminary findings at a scientific conference in October 1985 and provided them to the Committee on Passive Smoking that prepared the 1986 NRC Report.

The 1986 NRC Report cited Reynolds' research as support for the statement that "[i]n ETS, nicotine is present almost exclusively in the vapor phase." (U.S. Exh. 63,708 at 36). Similarly, the 1986 Surgeon General's Report stated that "nicotine … occurs almost exclusively in the vapor phase" of ETS and cited Reynolds' research for that proposition. (JE-063709 at 134).

Q: Did Reynolds' scientists publish the final results of that research?

A: Yes, JD-064500 is the final version of the paper presenting the results of that research, "Studies on the Vapor-Particulate Phase Distribution of Environmental Nicotine by Selective Trapping and Detection Methods" published in 1986 in the *Proceedings of the 79th Annual Meeting of the Air Pollution Control Association*.

Q: Does this paper identify the scientists' affiliation with Reynolds?

A: Yes, on the first page.

Q: Did Reynolds fund any outside researchers to conduct related research focusing on measuring nicotine in ETS?

A: Yes, Reynolds and later the Center for Indoor Air Research ("CIAR"), of which Reynolds was a member, funded Dr. Delbert Eatough at Brigham Young University to conduct work in this area.

Q: Did Dr. Eatough publish the work that was funded by Reynolds and CIAR?

A: Yes. Dr. Eatough published at least five articles or papers on this or closely-related topics: (a) an article entitled "Determination of Gas Phase Nicotine and 3-Ethenylpyridine, and Particulate Phase Nicotine in Environmental Tobacco Smoke With A Collection Bed - Capillary Gas Chromatography System" published in 1988 in the peer-reviewed *Journal of High Resolution Chromatography & Chromatography Communications*, a copy of which is

JD-047051; (b) a paper (of which I was a co-author) entitled "Sampling Gaseous Compounds In Environmental Tobacco Smoke" that was published in the *Proceedings of the 1988 EPA/APCA International Symposium on Measurement of Toxic and Related Pollutants* and a copy of which is JD-064498; (c) an article entitled "The Chemical Composition of Environmental Tobacco Smoke III. Identification of Conservative Tracers of Environmental Tobacco Smoke" published in 1989 in the peer-reviewed journal *Environment International*, a copy of which is JD-047052; and (d) a paper entitled "Use of Urine Nicotine and Cotinine Measurements to Determine Exposure of Nonsmokers to Sidestream Tobacco Smoke" presented at the Indoor Air 1990 Conference in Toronto, a copy of which is JD-080629. And, along with researchers from the Environmental Protection Agency, Harvard University School of Public Health, Yale University School of Medicine, and the University of Massachusetts School of Medicine, we also did a collaborative study in this area with Dr. Eatough that resulted in an article (of which I was a co-author) entitled "An Intercomparison of Sampling Techniques for Nicotine in Indoor Environments" published in 1990 in the peer-reviewed journal *Environmental Science & Technology*, a copy of which is JD-064481.

Q: Do these articles and papers acknowledge funding or involvement by Reynolds and/or CIAR?

A: Yes, they do.

Q: What were other steps in Reynolds' ETS-related research program?

A: We developed a method to measure nicotine in the concentrations it exists in indoor environments. As of 1985, there was no valid and approved scientific method capable of measuring nicotine at the levels found in ETS. Within a year, I led a team of Reynolds' scientists in developing a method capable of measuring nicotine in indoor environments. This

method is sufficiently sensitive to detect nicotine in environments where there has been only minimal smoking, which had not been possible previously.

Q: Did you publish the results of this research?

A: Yes. I published the results of that research in an article entitled "Improved Gas Chromatographic Determination of Nicotine in Environmental Tobacco Smoke" published in 1989 in the peer-reviewed journal *Analyst*, a copy of which is JD-064550. I also presented these results at a scientific conference in 1986.

Q: Did you do anything else with these results?

A: Yes, I sought to have them validated and approved by independent standard-setting organizations.

Q: Why did you do that?

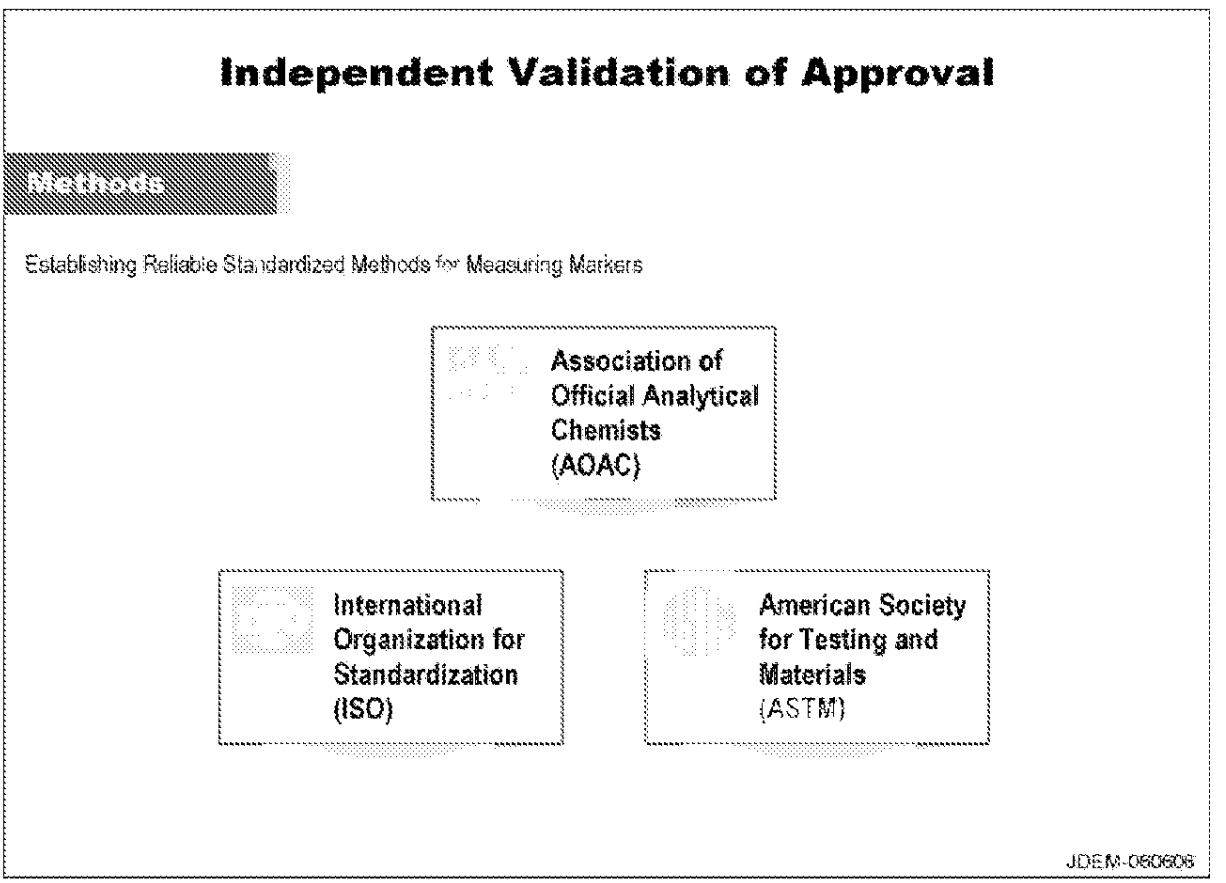
A: A method is much more valuable if it is validated and approved by one of the major standard-setting organizations.

Q: Why?

A: Because a major reason for developing a method for measuring things, particularly when the thing you are measuring is present in only minute quantities, as is often the case in analytical chemistry, is to make the method available to other researchers in the field and to facilitate meaningful comparisons. The hope is that other researchers will use the method, and it will become the "standard" method, which in turn allows different scientists' results to be compared with each other.

Q: Once you develop a method, how do you go about trying to have it validated and approved?

A: It's an involved and time-consuming process. Without going into details and as reflected in JDEM-060606, there are three primary organizations that do this, the Association of Official Analytical Chemists ("AOAC"), the American Society for Testing and Materials ("ASTM"), and the International Organization for Standardization ("ISO"). As I mentioned earlier, I am a member of AOAC and ASTM and am a representative at ISO.



Q: Turning back to your method for measuring ETS nicotine that you submitted for independent validation and approval, what happened -- was it validated and approved?

A: Yes, AOAC, ASTM, and ISO all validated and approved it. In fact, as of today, it is the only method for measuring ETS nicotine that has been validated and approved by any of those organizations.

Q: Has your method for measuring ETS nicotine been used by any federal agencies?

A: Yes, the National Institute for Occupational Safety and Health (NIOSH) used it in 2000 as the basis for its efforts to develop its own ETS nicotine method and used it in 1998 to measure ETS exposures in a New Jersey casino during an investigation ("Exposure of Casino Employees to Environmental Tobacco Smoke," *Journal of Occupational and Environmental Medicine* (1998) (JD-024810)).

Q: Did you attempt to test the method across different laboratories?

A: Yes. We did in experiments conducted with scientists from several other laboratories, including, among others, B.A.T. (UK & Export) Ltd., Brown & Williamson Tobacco Corporation, Lorillard Tobacco Company, and Philip Morris USA.

Q: Did you publish the results of that research?

A: Yes, we published the results of that research in two articles. The first article entitled "Gas Chromatographic Determination of Nicotine in Environmental Tobacco Smoke: Collaborative Study" was published in 1989 in the peer-reviewed *Journal of the Association of Official Analytical Chemists*, a copy of which is JD-064546. The second article entitled "Equivalency of Gas Chromatographic Conditions in Determination of Nicotine in Environmental Tobacco Smoke: Minicollaborative Study" was published in 1992 in the peer-reviewed *Journal of AOAC International*. JD-064548 is a copy of that article.

Q: Did the article disclose the authors' affiliations?

A: Yes.

Q: Other than developing your method for measuring ETS nicotine, did you do any other research relating to ETS nicotine?

A: Well, we were concerned about whether ETS nicotine was a good marker for ETS under real-world conditions. For example, ETS nicotine is in the gas phase and we were concerned that, over time, it might not be cleared or dissipate at the same rate as other ETS gas phase constituents or at the same rate as ETS particulate phase constituents. And when we looked at that, we found that, in fact, ETS nicotine has limitations as a marker.

Q: Did you publish results of that research?

A: Yes, (a) in 1990 in the *Proceedings of the 1990 EPA/A&WMA International Symposium* in a paper entitled "Problems With The Use of Nicotine As A Predictive Environmental Tobacco Smoke Marker," a copy of which is JD-064527; and (b) in 1992 in the peer-reviewed journal *Environmental Science & Technology* in an article entitled "Effect of Ventilation and Sampling Time on Environmental Tobacco Smoke Component Ratios," a copy of which is JD-064528.

Q: Did these papers reflect the authors' affiliation with Reynolds?

A: Yes, they did.

Q: What did these studies show?

A: In general terms, they showed that, over time, ETS nicotine goes through adsorption (*i.e.*, it deposits on solid surfaces) and then desorption (*i.e.*, it becomes a gas again). As a result, ETS nicotine had limitations as a marker for ETS because, in general, other ETS constituents tend to be cleared or dissipate in ventilated areas differently than does ETS nicotine. Accordingly, we started looking for other, better, ETS gas phase markers.

Q: We've been talking about ETS nicotine, a gas phase ETS marker. What had scientists been using as a particulate phase marker in the early 1980s?

A: Most commonly, respirable suspended particles, which are usually referred to as RSP.

Q: Did Reynolds' researchers evaluate RSP as an ETS marker?

A: Yes, we did.

Q: What did you find?

A: That RSP has limitations as a marker because it isn't unique to ETS.

Q: Did you publish results of that research?

A: Yes, in several papers, including one entitled "Evaluation of Methods For Estimating The Contribution of ETS to Respirable Suspended Particles" published in 1990 in the *Proceedings of the Fifth International Conference On Indoor Air Quality And Climate*," a copy of which is JD-064551.

Q: Does that paper reflect the authors' affiliation with Reynolds?

A: Yes.

Q: Given that the "traditional" gas and particulate phase ETS markers had limitations as markers, did you try to identify better ones?

A: Yes, we did.

Q: How did you go about identifying other ETS constituents that might be good ETS markers?

A: Among other things, we reviewed the published scientific literature and our own research relating to mainstream smoke and sidestream smoke, all with a view to finding constituents that might be good markers.

Q: What makes a good ETS marker?

A: The 1986 NRC Report (U.S. Exh. 63,708) sets out the main criteria (at page 70); namely, a substance should be (a) "unique or nearly unique to tobacco smoke so that other sources are minor in comparison;" (b) "a constituent of the tobacco smoke present in

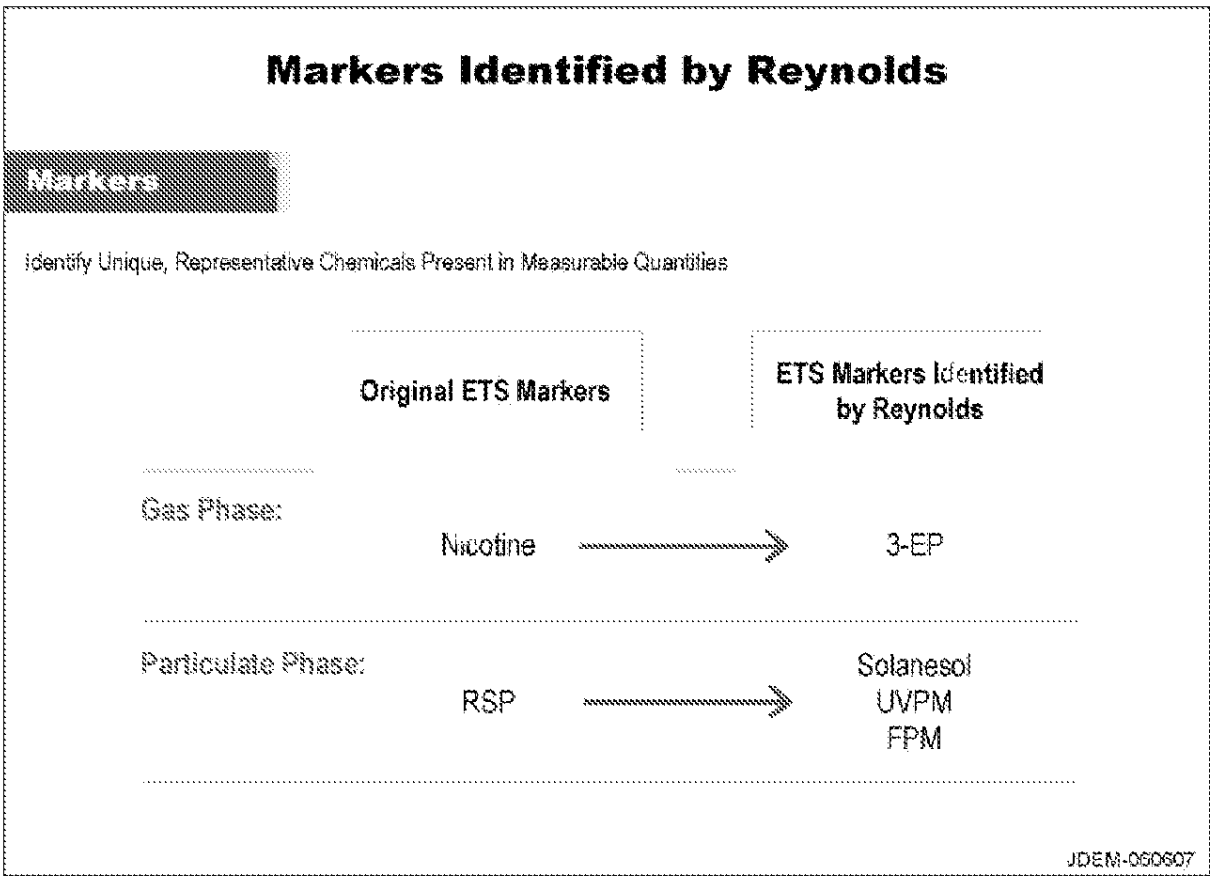
sufficient quantity such that concentrations of it can be easily detected in air, even at low smoking rates;" (c) "similar in emission rates for a variety of tobacco products;" and (d) "in a fairly consistent ratio to the individual contaminant of interest or category of contaminants of interest (e.g., suspended particulates) under a range of environmental conditions encountered and for a variety of tobacco products."

Q: Do you agree that these are the most relevant criteria?

A: Yes.

Q: Did Reynolds' scientists identify ETS markers that met these criteria?

A: Yes, we identified others. As reflected in JDEM-060607, a good gas phase ETS marker that was identified was 3-ethenylpyridine ("3-EP"), and we identified ultraviolet particulate matter ("UVPM"), fluorescing particulate matter ("FPM"), and solanesol as good particulate phase ETS markers.



Q: Did you publish results of that research?

A: Yes, we did. Publications that resulted from that work included (a) "Environmental Tobacco Smoke Monitoring With An Atmospheric Pressure Chemical Ionization Mass Spectrometer/Mass Spectrometer Coupled to Test A Chamber" presented in 1986 at the 79th Annual Meeting of the Air Pollution Control Association, a copy of which is JD-064586; (b) "Gas Chromatographic Determination of Solanesol in Environmental Tobacco Smoke (ETS)" published in 1988 in the peer-reviewed *Journal of High Resolution Chromatography*, a copy of which is JD-064544; (c) an article I mentioned previously, "Evaluation of Methods for Estimating The Contribution of ETS to Respirable Suspended Particles" published in 1990 in the *Proceedings of the Fifth International Conference on Indoor Air Quality and Climate*, a

copy of which is JD-064551; and (d) "Effect of Ventilation and Sampling Time on Environmental Tobacco Smoke Component Ratios" published in 1992 in *Environmental Science & Technology*, a copy of which is JD-064528.

Q: Did those publications reflect the authors' affiliation with Reynolds?

A: Yes.

Q: Did Reynolds' scientists develop methods to measure these ETS markers?

A: Yes, we did. We developed methods to measure, among other things, 3-EP, UVPM, FPM, and solanesol.

Q: Did you publish results of that research?

A: Yes. Publications that resulted from this work include (a) "Collection and Determination of Solanesol As A Tracer of Environmental Tobacco Smoke In Indoor Air" published in 1989 in the peer-reviewed journal *Environmental Science & Technology*, a copy of which is JD-064545; (b) "Measurement of Ethenylpyridine In Environmental Tobacco Smoke" published in 1990 in the *Proceedings of the 38th ASMS Conference on Mass Spectrometry and Allied Topics*, a copy of which is JD-064524; (c) "Comparative Evaluation of Diffusive and Active Sampling Systems for Determining Airborne Nicotine and 3-Ethenylpyridine" published in 1992 in the peer-reviewed journal *Environmental Science & Technology*, a copy of which is JD-064541; and (d) "Comparison of GC and LC for Determining Solanesol in Environmental Tobacco Smoke" published in 1992 in the peer-reviewed journal *LC-GC*, a copy of which is JD-064542.

Q: Did these publications reflect the authors' affiliation with Reynolds?

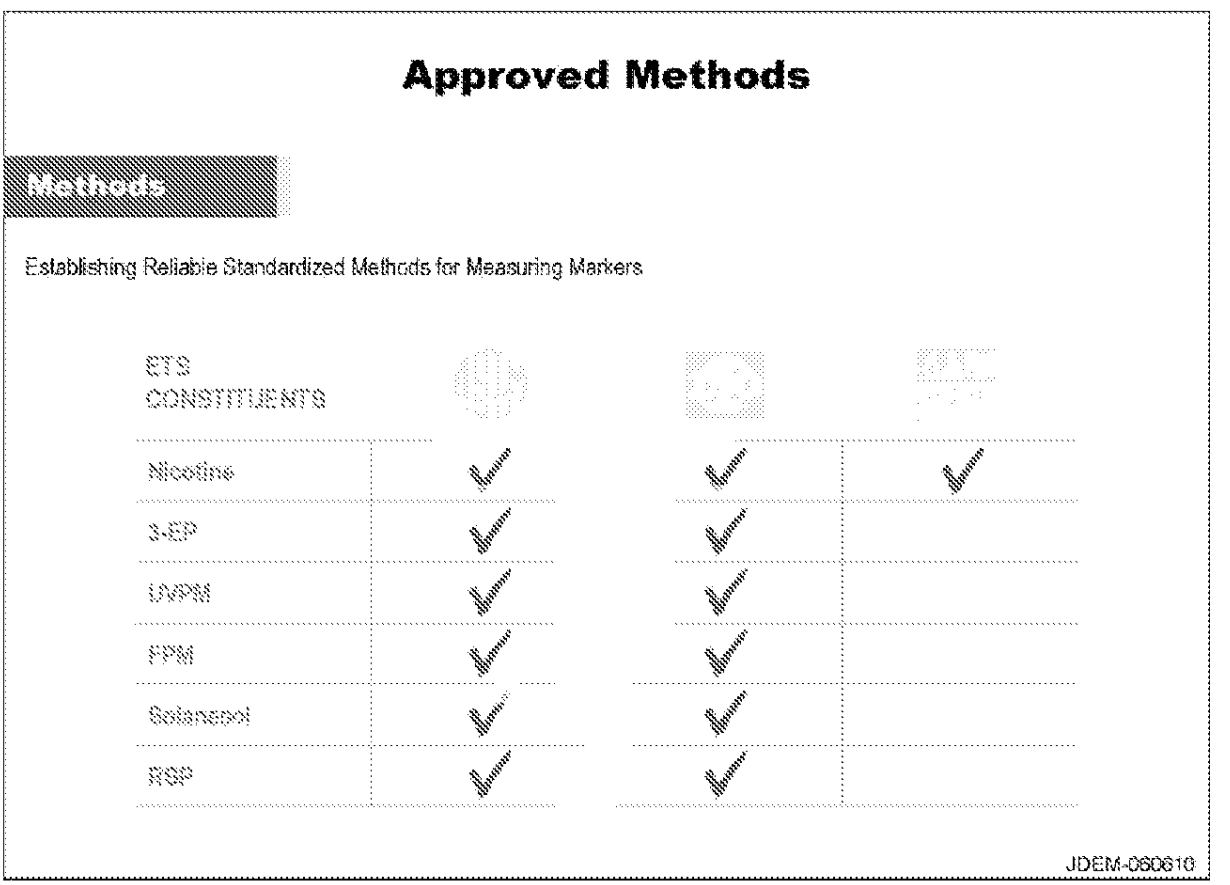
A: Yes.

Q: Did you have those methods validated and approved by standard-setting organizations?

A: Yes, we did.

Q: For how many ETS constituents have Reynolds' scientists had a method validated and approved by a standard-setting organization?

A: As reflected in JDEM-060610, Reynolds' scientists have had a method validated and approved by one or more of the three standard-setting organizations -- AOAC, ASTM, or ISO -- for 6 different ETS constituents -- nicotine, 3-EP, UVPM, FPM, solanesol, and RSP. Each was a substantial undertaking.



Q: You testified that the third phase of Reynolds' ETS-related research effort was "measurement." What did Reynolds' scientists do in this area?

A: Although I listed measurement third, I know from reviewing the relevant materials that Reynolds began doing measurement research on basic ETS constituents like carbon monoxide and particles well before we developed more reliable ETS markers and methods. In 1975, Reynolds contracted with Stanford Research Institute Laboratories ("SRI") to develop equipment for estimating public ETS exposure. In 1978, SRI provided Reynolds' scientists with a sampling device which was the size of a large suitcase.

Q: Was the SRI sampling device useful?

A: Not really. It was too heavy and cumbersome for use in public environments.

Q: What did Reynolds' scientists do next?

A: In the early 1980's, Reynolds' scientists improved on the SRI design and did a pilot study using a large, stationary device to monitor carbon monoxide and particles in indoor air. Although the equipment was an improvement, its obtrusive nature taught Reynolds' scientists that accurate measurement of ETS exposure would require the unobtrusive collection of samples. Otherwise, smokers changed their smoking behavior when they were aware of the measuring device by either avoiding smoking near it or by blowing smoke directly into it.

Q: You mentioned a pilot study. Why do you do pilot studies?

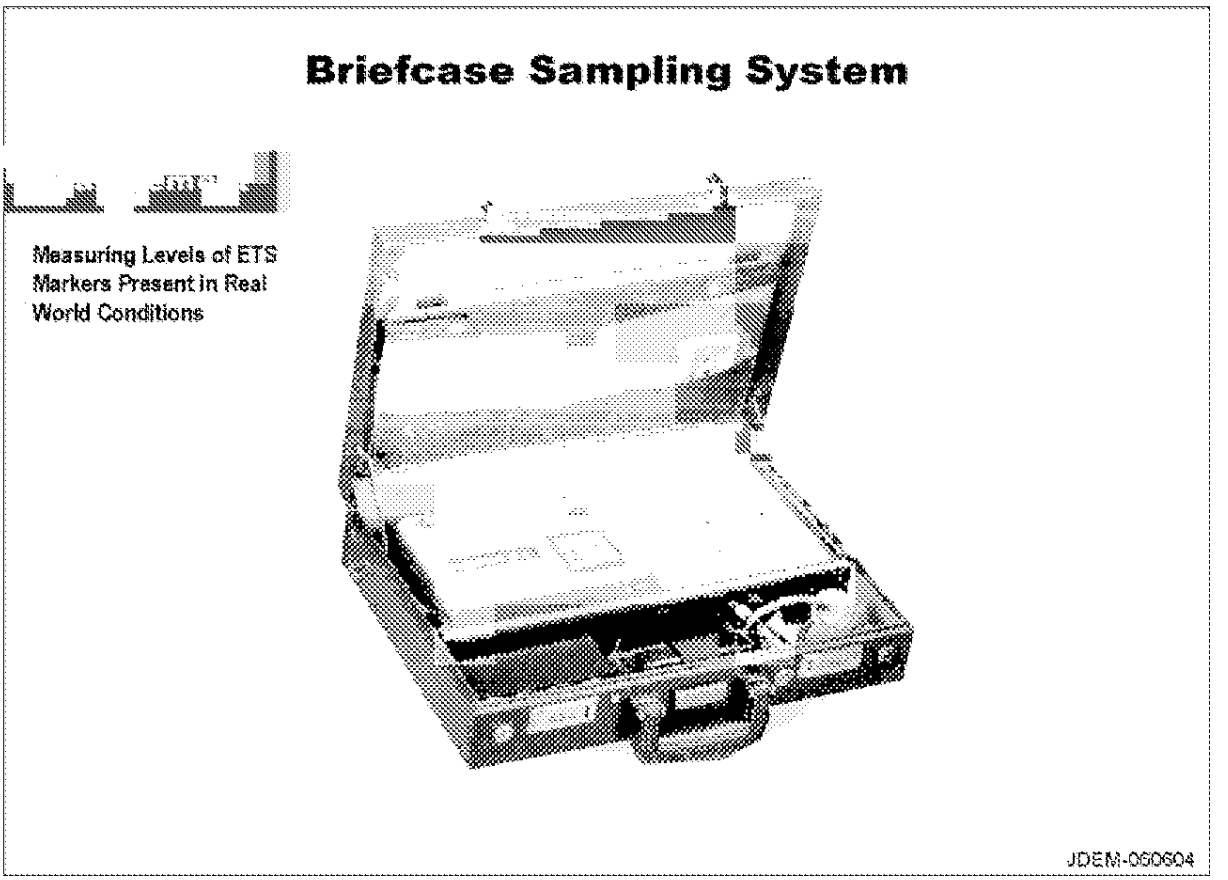
A: Pilot studies are fairly common in science. Very generally, a pilot study is a preliminary, smaller-scale study you perform to see if the study design and methodology work (*i.e.*, are the design and methodology likely to produce a meaningful and reliable result). If they don't, we can address and resolve any such issues before spending larger sums of money on a full study.

Q: In your experience, who made decisions about whether to conduct pilot studies and, when they were conducted, about whether and, if so, how to proceed with a full study?

A: In my experience, scientists always made decisions about whether to conduct a pilot study in the first instance and, after we conducted pilot studies, scientists always made decisions about whether and, if so, how to proceed with a full study.

Q: Turning back to Reynolds' ETS measurement studies, what was the next step?

A: In 1986 and as shown in JDEM-060604, Reynolds' scientists and engineers developed an unobtrusive, portable sampling system contained in an ordinary briefcase and that was improved over time. By mid-1986, because we had already begun to develop methods for some of the ETS markers, the portable air sampling system ("PASS") was configured to sample nicotine, RSP, and particles for UVPM analysis and to monitor carbon monoxide. Reynolds patented the PASS sampling system, and a few were produced and sold to outside contractors and other tobacco companies.



Q: Did Reynolds' scientists use these PASS briefcase samplers to measure ETS levels in real-world environments?

A: Yes. We used the PASS briefcase to survey ETS in offices, restaurants, grocery stores, and passenger cabins of commercial aircraft. The object of these surveys was to provide information about ETS levels in real-world environments.

Q: Did you publish results of that research?

A: Yes. Results of these studies are described in (a) "Estimation of Effect of Environmental Tobacco Smoke on Air Quality within Passenger Cabins of Commercial Aircraft" published in 1987 in the peer-reviewed journal *Environmental Science & Technology*, a copy of which is JD-064557, (b) "Results from Measurements of Nicotine in a

Tavern" published in 1989 in the *Proceedings of the EPA/A&WMA International Symposium on Measurement of Toxic and Related Air Pollutants*, a copy of which is JD-064558; (c) "Results from Surveys of Environmental Tobacco Smoke In Restaurants In Winston-Salem, North Carolina" published in 1990 in the *Proceedings of The Fifth International Conference on Indoor Air Quality and Climate*, a copy of which is JD-064554; (d) "Estimation of Effect of Environmental Tobacco Smoke on Air Quality Within Passenger Cabins of Commercial Aircraft. II" published in 1990 in the book *Indoor Air Quality and Ventilation*, a copy of which is JD-064555; and (e) "Results From Surveys of Environmental Tobacco Smoke in Offices and Restaurants" published in 1990 at pages 99-104 of the book *Indoor Air Quality*, a copy of which is U.S. Exh. 87,398. The fourth item I mentioned was co-authored with scientists from Philip Morris USA.

Q: Were the authors' affiliations reflected in these published articles.

A: Yes.

Q: What ETS levels were reported in the PASS briefcase study of ETS on airplanes that was published in JD-064557?

A: The results are reported in Tables I and II at pages 996 and 997. To the best of my knowledge, the measured levels of ETS nicotine in that study are the highest reported in the published literature looking at ETS nicotine levels on aircraft.

Q: Did Reynolds' scientists continue to use the PASS briefcase after these studies?

A: Not very much; instead, we developed better sampling devices.

Q: What types of devices?

A: Because we thought that samples collected directly on the person would give the most accurate measure of ETS exposure, Reynolds' scientists evaluated personal sample collection

devices that required no pump and could be attached to a person's clothing. I was the lead researcher for Reynolds on this project.

Q: Did you publish anything about these devices in the scientific literature?

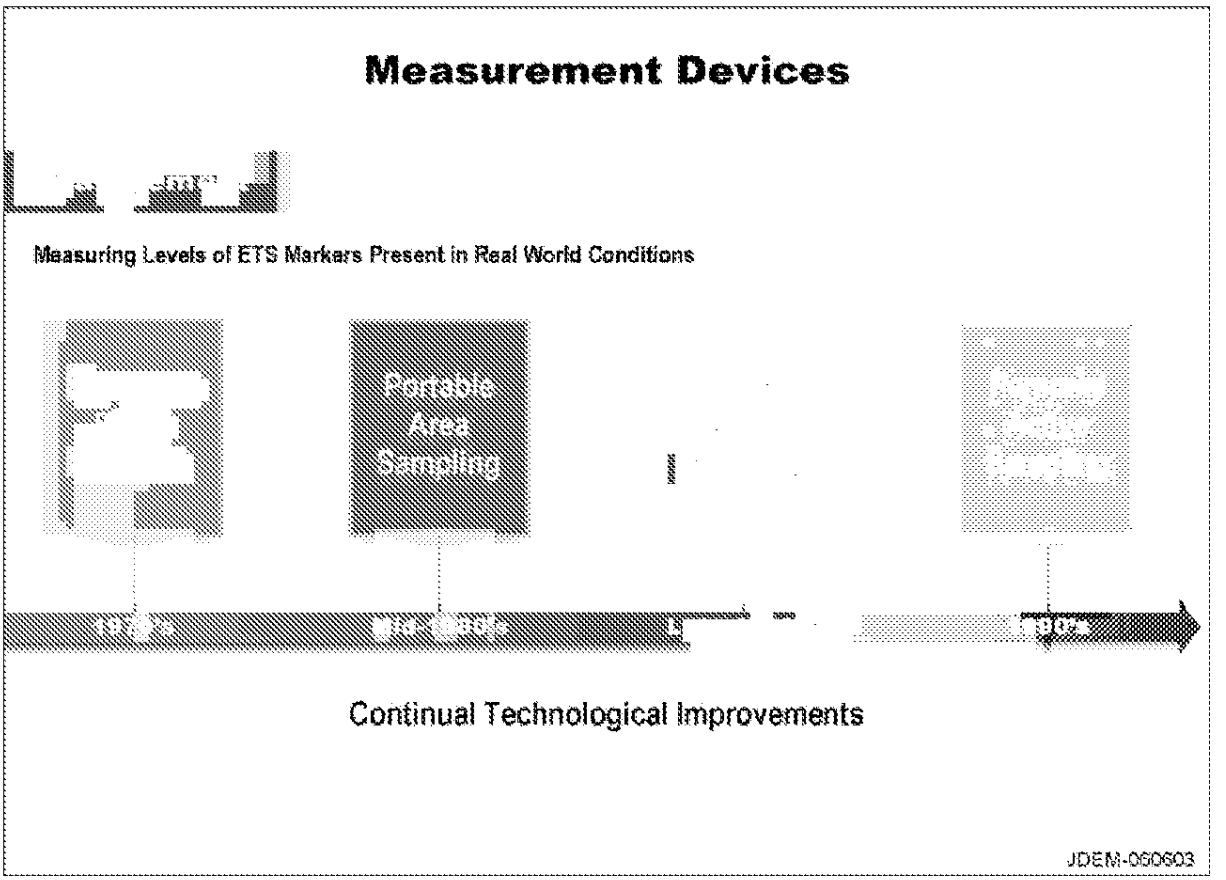
A: Yes. We published our evaluation of a stainless steel passive sampling device that, based on our analysis, was unsatisfactory in a paper entitled "Evaluation of a Personal Passive Sampling Device for Determining Exposure to Nicotine in Environmental Tobacco Smoke" published in 1989 in the *Proceedings of the 1989 EPA/AWMA International Symposium: Measurement of Toxic and Related Air Pollutants*, a copy of which is JD-064553. We also published an article describing our work on the development and evaluation of an all-plastic personal sampling device in 1992 in *Environmental Science & Technology*, a peer-reviewed scientific journal. That article is entitled "Comparative Evaluation of Diffusive and Active Sampling Systems for Determining Airborne Nicotine and 3-Ethenylpyridine," and JD-064541 is a copy of that article.

Q: Does this published article reflect your affiliation with Reynolds?

A: Yes, it does.

Q: Were there any further improvements?

A: Yes, as reflected in JDEM-060603 that depicts the advances in measurement devices over time, we made an improved personal sampling device that uses small pumps to collect both gas and particle samples simultaneously. We patented and then licensed this technology to a manufacturer that sold at least 100 of them.



Q: Did you publish anything about this device in the scientific literature?

A: Yes, we published an article about this device in 1996 in the peer-reviewed journal *Environmental Technology*. It was entitled "Personal Monitoring System for Measuring Environmental Tobacco Smoke Exposure," and JD-064535 is a copy of that article.

Q: Did Reynolds' scientists use these personal sampling devices to conduct studies of real-world ETS exposures?

A: Yes, many times.

Q: Did you publish results of such studies in the scientific literature?

A: Yes, we published the results of real-world exposure studies in which personal monitors were used, including (a) "Multiple Measurements of Personal ETS Exposure In A

Population-Based Survey of Nonsmoking Women in Columbus, Ohio" published in 1993 in the *Proceedings of the 6th International Conference on Indoor Air Quality and Climate*, a copy of which is JD-064536; (b) "Determination of Volatile Organic Compounds and ETS Apportionment In 49 Homes" published in 1995 in the peer-reviewed journal *Environment International*, a copy of which is JD-064505; and (c) "Determination of Volatile Organic Compounds and Respirable Suspended Particulate Matter in New Jersey and Pennsylvania Homes and Workplaces" published in 1996 in the peer-reviewed journal *Environment International*, a copy of which is JD-064506.

Q: Do these articles reflect the scientists' affiliation with Reynolds?

A: Yes, they do.

Q: In very general terms, what did Reynolds' measurement studies show about non-smokers ETS exposures?

A: Each study obviously set forth its own findings in a detailed manner. At a general level, however, we found that the particular methodologies used to design the study and to measure exposure are important and that differing approaches to study design and exposure measurement can have important effects on a study's results. As we learned more about markers, learned more about the methods for measuring them, and improved our measuring technology -- for example, as we moved from area samplers such as the PASS briefcase to passive and then active personal samplers -- we obtained what I believe are substantially more accurate and reliable measurements of real-world exposures. And, in general, we determined that, as compared to estimates of non-smokers' exposures that had been calculated in the late 1970s and early 1980s based on theoretical models and strings of assumptions, actual exposures are, in general, substantially lower.

Q: What estimates from the late 1970s and early 1980s are you referring to?

A: There were many. For example, in an article published in 1980 in *Science* entitled "Indoor Air, Tobacco Smoke, and Public Health" that is JD-003049, two researchers, James Repace and Alfred Lowery, had used a few RSP measurements and a series of assumptions to construct a model yielding exposures for an office worker and nightclub musician of, respectively, 5 and 27 cigarettes per day. Although the 1986 NRC Report (U.S. Exh. 63,708) and the 1986 Surgeon General's Report (JE-063709) discussed these researchers' results at some length (U.S. Exh. 63,708 at 93-94; JE-063709 at 159-60, 165), we found that measured exposures in the real world were much lower.

Q: Did you ever attempt to translate the results of Reynolds' exposure studies into cigarette equivalents?

A: Yes, some of our studies did that. For example, our estimates of ETS exposures for nonsmokers in offices, restaurants, and planes based on actual measurements were 2 or less cigarettes per month ("Estimation of Effect of Environmental Tobacco Smoke on Air Quality within Passenger Cabins of Commercial Aircraft" (JD-064557); "Results From Surveys of Environmental Tobacco Smoke in Offices and Restaurants" (U.S. Exh. 87,398)). Our estimate based on measurements in a nightclub was 10 cigarettes per month ("Results from Measurements of Nicotine in a Tavern" (JD-064558)).

Q: How did these findings compare to Repace and Lowery's findings?

A: Rather than the 5 cigarettes per day that Repace and Lowery calculated for a nonsmoking office worker, we measured that exposure and found it to be less than 2 cigarettes per month. And, rather than the 27 cigarettes per day exposure that Repace and

Lowery calculated for a nightclub, we measured that exposure and found it to be about 10 cigarettes per month.

Q: What would those cigarette equivalents translate into in terms of annualized exposure?

A: Repace and Lowery's calculated figures would have placed nonsmoker exposures at between roughly 1,800 and 9,800 cigarette equivalents per year, while our measurement studies placed nonsmoker exposures at roughly 20 to 120 cigarette equivalents per year. Of course, a pack-a-day smoker smokes more than 7,000 cigarettes per year.

Q: Is cigarette equivalents a precise way to express ETS exposure?

A: No, it's a rough one. There is no perfect way to make such comparisons because the ratios of constituents in ETS and mainstream smoke vary and, accordingly, the choice of ETS marker used for computing cigarette equivalents affects the results. Nevertheless, it does provide a convenient way of making comparisons and of putting the amounts of ETS most people are exposed to in the real world into rough perspective.

Q: Were there any other general findings across Reynolds' ETS exposure measurement studies?

A: Another thing we found pretty consistently across the studies was that non-smokers' levels of exposure were several times greater in homes with smoking spouses than in workplaces where smoking was permitted, no matter how that exposure was measured.

Q: Has Reynolds been involved in exposure measurement studies conducted by outside scientists?

A: Yes. Aside from studies where Reynolds (and other cigarette manufacturers) merely provided funding through The Council for Tobacco Research - U.S.A., Inc. or The Center for

Indoor Air Research ("CIAR"), Reynolds was involved in Oak Ridge National Laboratory's ("ORNL") exposure study, the full results of which first were published in 1996 in the peer-reviewed *Journal of Exposure Analysis and Environmental Epidemiology*. The article containing those results is entitled "Exposure to Environmental Tobacco Smoke In Sixteen Cities In The United States Determined By Personal Breathing Zone Air Sampling" (the "16 Cities Study"). JD-044272 is a copy of that article.

Q: How was Reynolds involved in that study?

A: As an initial matter, CIAR, of which Reynolds was a member, funded the 16 Cities Study, and CIAR's staff and its board of directors, which was composed of scientists from CIAR's member companies, were involved in the preliminary discussions with the ORNL researchers about conducting the study. But I am referring to the facts that Reynolds' laboratories conducted the study's laboratory analytical work and that several of us at Reynolds were involved in the study's field work.

Q: Were the facts that CIAR funded the 16 Cities Study and that Reynolds performed the laboratory and field work disclosed in the published article?

A: Yes. CIAR's funding and the laboratory and field work by several Reynolds employees, myself included, were acknowledged on page 500. The fact that Reynolds performed the laboratory analytical work was mentioned several times in the article, including at pages 475, 481, and 483.

Q: Did ORNL have an existing capability to conduct the laboratory analytical work for the 16 Cities Study?

A: No, it either had to build new laboratories to do that work or contract it out. It ended up contracting it out to Reynolds.

Q: Did the ORNL researchers do anything to ensure and test the reliability of Reynolds' analytical work?

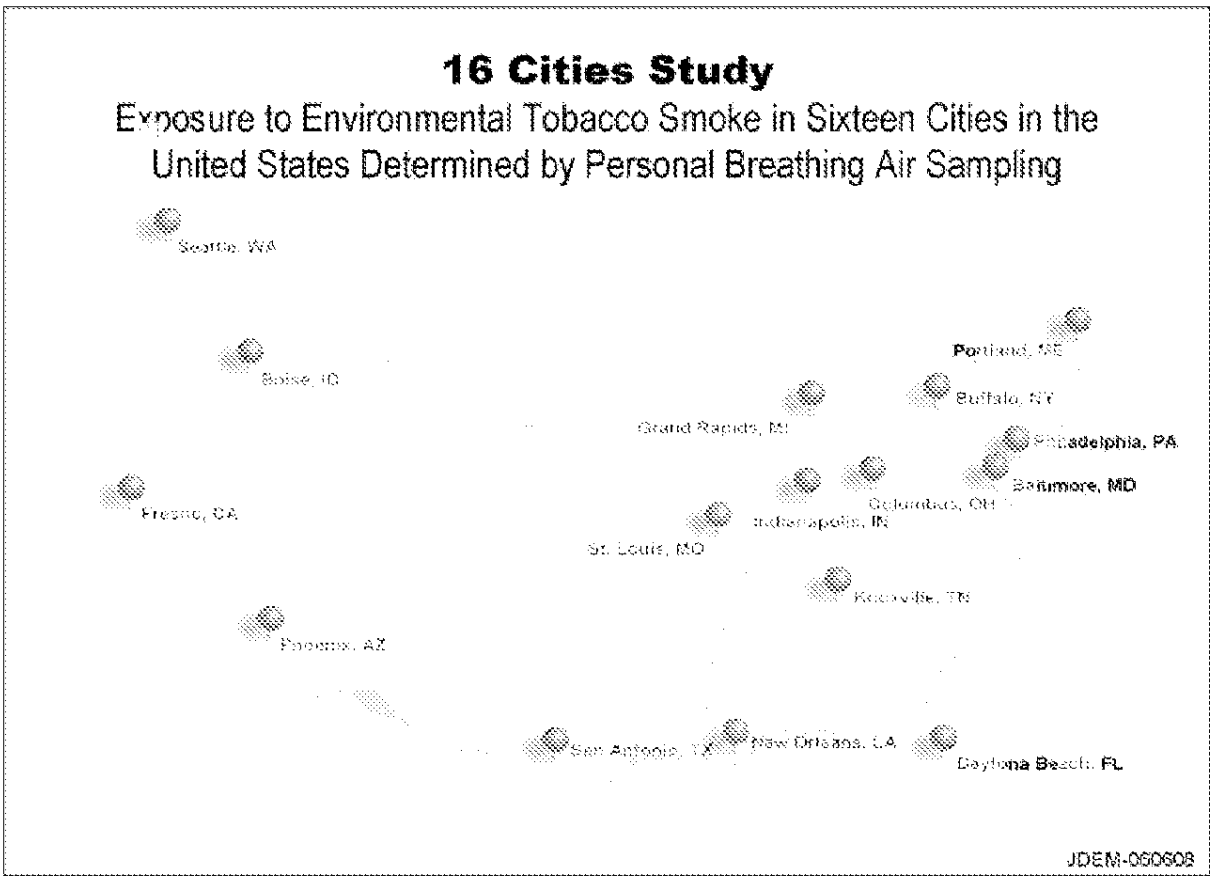
A: Yes, there were extensive quality control procedures to ensure reliability.

Q: Did Reynolds' scientists and technicians perform the analytical work accurately?

A: Yes, of course.

Q: How did the 16 Cities Study compare with the exposure studies Reynolds had conducted?

A: The sampling methodology was similar to that used in Reynolds' studies, and the analytical methods were the same. However, the 16 Cities Study was, as compared to Reynolds' studies, much larger -- it included roughly 1,600 subjects -- and, as reflected in JDEM-060608, it covered many more locations -- 16 in all. Reynolds' exposure studies have been substantially smaller in that, as a rule, they did not have more than 100 subjects each. Reynolds' exposure studies had also been conducted in substantially fewer locations, typically one or two. While the 16 Cities Study was not, of course, completely representative, it both was and remains the largest and most representative ETS exposure study of which I am aware.



Q: What about the results -- how did the 16 Cities Study's results compare with the results of Reynolds' exposure studies in general terms?

A: Again, the results are fairly detailed and are set forth in full in the published article, but they generally are similar. The 16 Cities Study found overall levels of exposure comparable to, but somewhat lower than Reynolds' exposure studies and found that, for subjects exposed to ETS away-from-work or at work, away-from-work exposures generally were greater. The highest 10% of work-exposed subjects in the 16 Cities Study had exposures comparable to subjects living in smoking residences, but their exposures were substantially lower than what had been estimated by OSHA.

Q: We've talked about ETS-related research relating to ETS markers, methods, and measurements. Has Reynolds conducted any other types of ETS-related studies?

A: Yes, we conducted toxicological testing -- animal inhalation testing -- in which we exposed rats to diluted sidestream smoke administered in amounts that sought to approximate various levels of ETS exposure.

Q: Were the results of those studies published?

A: Yes. The results of one study were published in 1992 in *Fundamental and Applied Toxicology*, a peer-reviewed journal. The article was entitled "Fourteen-Day Inhalation Study in Rats, Using Aged and Diluted Sidestream Smoke from a Reference Cigarette. Part I: Inhalation Toxicology and Histopathology." JD-044273 is a copy of that article. The results of another study were published in 1993 in *Inhalation Toxicology*, a peer-reviewed journal. The article was entitled "Subchronic Inhalation Study In Rats, Using Aged and Diluted Sidestream Smoke From A Reference Cigarette." JD-061315 is a copy of that article.

Q: Did those articles reflect the authors' affiliation with Reynolds?

A: Yes.

Q: Would you describe what those studies found?

A: Generally, these studies showed no effects at levels designed to simulate real-world levels of exposure and showed either no or minimal effects at substantially elevated levels of exposure.

Q: You previously said that you personally have published over 60 articles while at Reynolds, and we have discussed several of them here. How do you decide what research results you will publish?

A: Assuming there is no competitively-sensitive or proprietary information involved, I generally publish whatever I believe is worthy of publication, typically results that are in some way new or add to the state of scientific knowledge and that would be likely to be of interest to the outside scientific community.

Q: In all, how many articles, papers, or letters to the editor have Reynolds' scientists published relating generally to ETS or ETS issues?

A: More than 150 in all. JD-067973 is a summary exhibit listing those articles, papers, and letters to the editor.

Q: Have you ever falsified or fabricated research results?

A: Of course not.

Q: Are you aware of any instance during your tenure at Reynolds' Research and Development Department in which research results were falsified or fabricated?

A: No.

Q: Have you ever attempted to hide your affiliation with Reynolds in your publications or public statements relating to ETS?

A: No.

Q: Now I'd like to turn to Reynolds' judgments about ETS exposure and disease causation. In your experience, who has been responsible for developing Reynolds' judgments regarding ETS and disease causation?

A: Ultimately, of course, it is the company's executive management's decision. My experience, however, has been that Reynolds' executive management seeks and then follows Reynolds' scientists' advice and input in developing the company's judgments regarding ETS and disease causation. With respect to ETS, Reynolds' chemists (myself included), biologists,

engineers, toxicologists, and statisticians have advised executive management regarding the state of ETS science and what our judgments and assessments of that science are.

Q: What is Reynolds' judgment or opinion regarding ETS exposure and disease causation in children?

A: Reynolds' judgment or opinion with respect to ETS and disease causation in children is that many studies have reported that young children in smoking households have an increased incidence of respiratory problems, such as bronchitis, asthma and middle-ear infections. Some studies have also reported that secondhand smoke is one of many factors that have been identified as possibly contributing to sudden infant death syndrome (SIDS). Based on the overall body of scientific evidence, common sense dictates, and Reynolds believes, that parents and others should minimize the exposure of infants and young children to tobacco smoke and other airborne irritants.

Q: Do you agree with this?

A: Yes.

Q: Do you believe this statement is false or untrue?

A: No.

Q: Have other Reynolds scientists knowledgeable about and familiar with ETS science expressed their agreement with this statement to you?

A: Yes, many have.

Q: Have other Reynolds scientists knowledgeable about and familiar with ETS science expressed their disagreement with this statement?

A: Not to my knowledge.

Q: What is Reynolds' judgment or opinion regarding ETS exposure and adults?

A: Reynolds' judgment or opinion with respect to ETS exposure and disease causation in adults is that, considering all of the evidence, it seems unlikely that secondhand smoke presents any significant harm to otherwise healthy adults at the very low concentrations commonly encountered in homes, offices and other places where smoking is allowed. Reynolds recognizes that exposure to high concentrations of secondhand smoke may cause temporary irritation, such as teary eyes, and even coughs and wheezing in some adults. In addition, there is evidence that secondhand smoke, like other airborne irritants, or allergens such as pollen and dust, may trigger attacks in asthmatics. Given the potential for these effects, Reynolds believes that people who don't want to be exposed to secondhand smoke should be able to avoid it.

Q: Is that your judgment or opinion too?

A: Yes, it is.

Q: Do you believe that judgment is false or untrue?

A: No.

Q: Have other Reynolds scientists knowledgeable about and familiar with ETS science expressed their agreement with this judgment or opinion to you?

A: Yes, many have.

Q: Have other Reynolds scientists knowledgeable about and familiar with ETS science expressed their disagreement with this judgment or opinion?

A: Not to my knowledge.

Q: You are aware that the 1986 Surgeon General's Report (JE-063709), the 1986 NRC Report (U.S. Exh. 63,708), and the 1986 *IARC Monograph on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco* (U.S. Exh. 64,066) (the " 1986

IARC Monograph") all concluded that exposure ETS causes lung cancer in nonsmoking adults?

A: Yes, I am.

Q: And you are aware that, in the 1990s, several public health organizations concluded that ETS causes coronary heart disease in nonsmoking adults?

A: Yes, I am.

Q: But you don't agree with those conclusions about ETS having been established as a cause of lung cancer and coronary heart disease in nonsmoking adults?

A: My assessment of the evidence differs. As I said before, my judgment is that it is unlikely that ETS causes significant harm to otherwise healthy nonsmoking adults.

Q: Why?

A: There are several reasons. First, I'm an analytical chemist and, from my perspective, we knew very little about what ETS exposures were in the real world in the mid-1980s when the 1986 Surgeon General's Report, the 1986 NRC Report, and the 1986 IARC Monograph concluded that the evidence supported the conclusion that ETS causes lung cancer in nonsmokers. Indeed, as I mentioned before, the 1986 NRC Report called for additional research on, among other things, that very issue. Based on what we knew then, it seemed to me that real-world ETS exposures were likely to be only a very small fraction of the tobacco smoke exposure experienced by smokers. It is an old saying in science that "the dose makes the poison." Based on what we knew and suspected about ETS exposures in 1986, they just appeared too low to be of significant concern to otherwise healthy adults.

Q: Did your views change based on the results of Reynolds' ETS exposure research?

A: No, our research, if anything, confirmed my view that real-world ETS exposures typically are a very small fraction of the tobacco smoke exposure experienced by smokers. These results, coupled with the very weak epidemiology and the toxicological information available, underlie my judgment that it is unlikely that ETS causes harm to otherwise healthy nonsmoking adults.

Q: What do you mean when you say you believe that the epidemiology is "weak"?

A: The epidemiological studies examining ETS and lung cancer have not shown a consistent, strong association.

Q: Why do you say that?

A: Because, among other things, the epidemiological studies (a) didn't look at actual exposures, they looked at proxies for exposure -- generally being married to a smoker; (b) reported very low relative risks that were only slightly above 1.0 -- the relative risk reflecting no increased risk; (c) with a few exceptions, did not have results that were statistically significant and, therefore, did not exclude the null hypothesis (*i.e.*, no effect); (d) sometimes reported negative overall relative risk point estimates; and (e) failed to properly or adequately adjust for biasing and confounding factors (*e.g.*, the bias introduced when former or current smokers respond to questionnaires by claiming to be never smokers). This was true in 1986, and it remains true today.

Q: I'd like to turn to the Environmental Protection Agency's risk assessment. Do you recall that the EPA released drafts of its risk assessment for public comment?

A: Yes, I do.

Q: When were those drafts released?

A: In June 1990, the EPA released a draft risk assessment dated as of May 1990 entitled *Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children* (the "1990 Draft EPA Risk Assessment"), a copy of which is JD-004716. In June 1992, the EPA released another draft risk assessment dated as of May 1992 labeled as a "SAB Review Draft" that was entitled *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders* (the "1992 Draft EPA Risk Assessment"), a copy of which is JD-004717.

Q: Did the EPA solicit public comments on the draft risk assessments?

A: Yes, it did. It published a notice in the *Federal Register* calling for comments on the 1990 Draft EPA Risk Assessment and published a notice stating that comments on the 1992 Draft EPA Risk Assessment received within a fairly short period would be submitted for consideration by the EPA's Scientific Advisory Board ("SAB").

Q: Did Reynolds submit comments on the 1990 Draft EPA Risk Assessment?

A: Yes, Reynolds submitted comments dated October 1, 1990 that are JD-023795.

Q: Were you involved in preparing those comments?

A: Yes, I was.

Q: Did Reynolds submit comments on the 1992 Draft EPA Risk Assessment?

A: Yes, Reynolds submitted comments dated July 6, 1992 that totaled more than 200 pages and are JD-023796.

Q: Were you involved in preparing those comments?

A: Yes, I spent a substantial amount of time reviewing the draft report and preparing comments, as did others at Reynolds. I authored or co-authored some of the documents that were included within Reynolds' comments.

Q: Were Reynolds' comments intended to influence the EPA in its decision-making regarding the draft and final risk assessments?

A: Yes, of course.

Q: Were Reynolds' comments on the 1990 EPA Draft Risk Assessment and 1992 Draft EPA Risk Assessment, in general terms, critical of the scientific conclusions reached in those draft reports?

A: Yes, they were critical. In general, Reynolds' comments stated that, in Reynolds' view, the underlying science did not support the proposed conclusion that ETS should be classified as a Group A carcinogen. We hoped to convince the EPA to alter that proposed conclusion.

Q: Did you agree with Reynolds' comments on those draft reports?

A: Yes, I did. The EPA's ultimate conclusion -- that ETS should be classified as a Group A carcinogen -- was based on many underlying scientific conclusions with which I did not agree.

Q: Was that your genuinely-held belief?

A: Yes.

Q: Did the EPA release a final version of its risk assessment?

A: Yes. In 1993, the EPA released the final version of the risk assessment dated as of December 1992 that, as with the 1992 EPA Draft Risk Assessment, was entitled *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders* (the "EPA Risk Assessment"), a copy of which is U.S. Exh. 88,654.

Q: Did the EPA Risk Assessment, as issued, address the issues Reynolds raised in its comments on the earlier drafts?

A: It may have mentioned some of the issues we raised, but generally no. Certainly the ultimate conclusion that ETS should be classified as a Group A carcinogen did not change.

Q: What were some of Reynolds' criticisms of the draft reports and the EPA Risk Assessment?

A: One of Reynolds' criticisms was that, in some chapters, the EPA found it to be biologically plausible that ETS is a carcinogen based on similarities between and among ETS, mainstream smoke, and sidestream smoke, while in other chapters the EPA found that ETS and mainstream smoke are dissimilar for purposes of calculating population risk.

Q: What were some of Reynolds' other criticisms?

A: We had a number of more specific criticisms such as our views that EPA had not properly considered and addressed the potential effects of confounding and bias. We also stated our view that the EPA should not have substituted a two-tailed, 90% confidence interval for the standard two-tailed, 95% confidence intervals used in the 1990 Draft EPA Risk Assessment and in all (or virtually all) of the underlying studies. We also expressed reservations about the manner in which the EPA elected to discount or not consider certain studies.

Q: You mentioned that you authored some of Reynolds' comments on the 1992 EPA Draft Risk Assessment. What comments were those?

A: The comments I authored or co-authored related to Chapters 5 and 6 of the 1992 EPA Draft Risk Assessment. Two of my colleagues and I commented on Chapter 5, which related to the EPA's effort to adjust its data to correct for misclassification bias (*i.e.*, the statistical bias resulting from former and current smokers reporting themselves as never smokers in questionnaires used in ETS epidemiological studies). My comments on Chapter 6 critiqued

the EPA's background correction factor, which was an adjustment of the relative risks for ETS exposure in the control populations of the epidemiological studies.

Q: Did persons unrelated to Reynolds raise criticisms of the EPA Risk Assessment similar to those that Reynolds raised in its comments?

A: Yes, several others did. For example, researchers from the Congressional Research Service testifying before a Senate subcommittee raised many similar and related concerns about the EPA Risk Assessment. A copy of the Congressional Research Service researchers' testimony is JD-003086. In addition, a United States District Judge criticized it in an opinion relating to his order granting Reynolds and other plaintiffs partial summary judgment in an action against the EPA relating to the EPA Risk Assessment. A copy of the United States District Court Judge's opinion, *Flue-Cured Tobacco Stabilization Cooperative Corporation v. United States Environmental Protection Agency*, 4 F. Supp. 2d 435 (M.D.N.C. 1998), is JD-001702. I understand that an appellate court subsequently vacated the District Court Judge's order on jurisdictional grounds, but did not address or consider the substance of the District Court Judge's findings. *Flue-Cured Tobacco Stabilization Coop. Corp. v. United States EPA*, 313 F.3d 852 (4th Cir. 2002), *vacating* 4 F. Supp. 2d 435 (M.D.N.C. 1998).

Q: I'd like to turn to the Occupational Safety and Health Administration's ("OSHA") proposed rule regarding workplace smoking. Are you aware that on September 20, 1991, as reflected in JD-080318, OSHA issued a public request for information on indoor air in occupational environments in order to determine whether regulatory action was appropriate?

A: Yes, I am.

Q: Did Reynolds respond to OSHA's request for information?

A: Yes, it did. JD-023792 is a copy of Reynolds' March 24, 1992 written response to that request.

Q: Did you participate in preparing Reynolds' written response to OSHA's request for information?

A: Yes, I did.

Q: Did Reynolds provide additional information to OSHA?

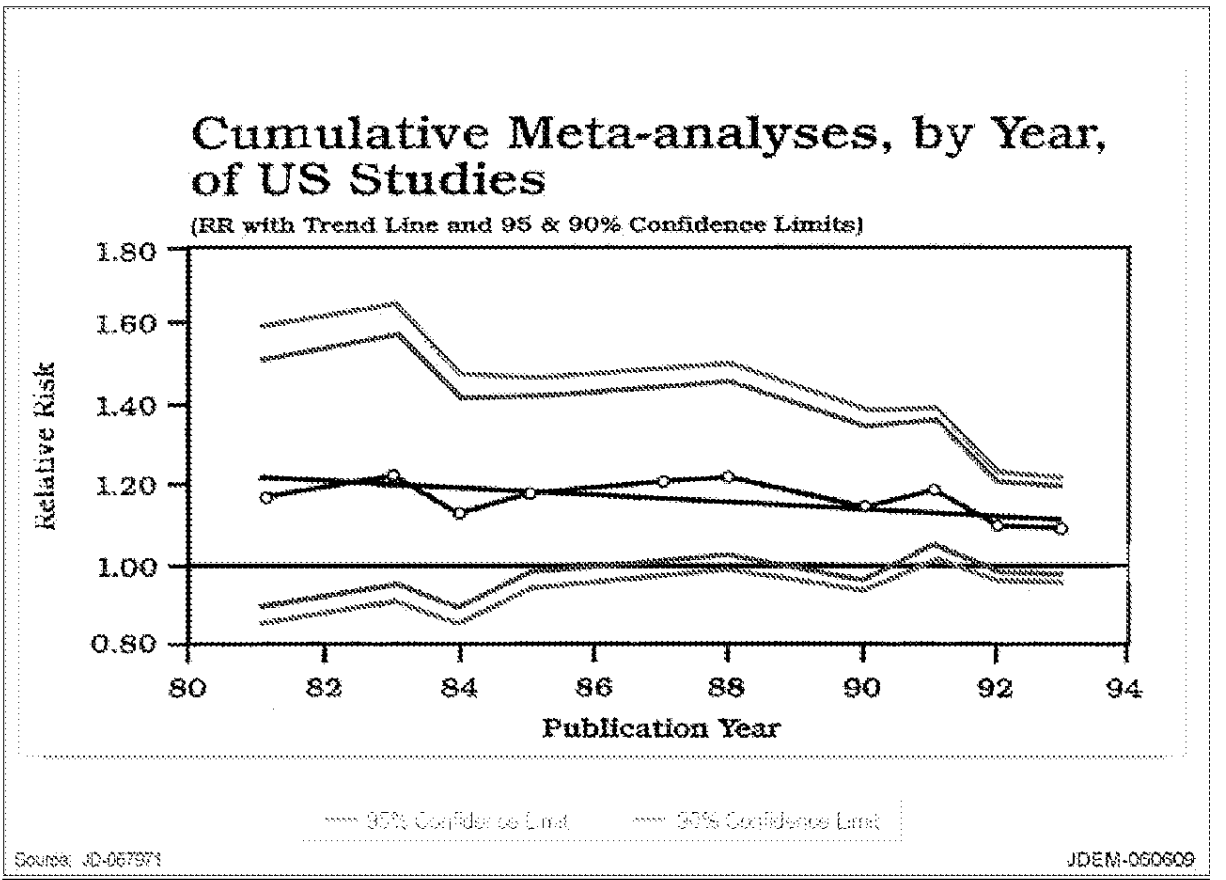
A: Yes, three of us from Reynolds -- Dr. Stephen Sears, Thomas Steichen, and I -- made an oral presentation to OSHA on May 5, 1993 in which we reviewed the meta-analysis in the EPA Risk Assessment and explained the implications of that report on workplace ETS issues. JD-067971 is a copy of the slides from that presentation.

Q: What did you tell OSHA about the EPA Risk Assessment?

A: As reflected in the slide presentation, there were a number of points regarding, among other things, confounding, bias, and background adjustment.

Q: Anything else?

A: Yes, we presented the results of our reanalysis of the EPA's meta-analysis of the U.S. epidemiological studies over time. As reflected in JDEM-060609, which reproduces and highlights one of the slides in our presentation, that analysis showed that, for the period from 1981 to 1993, (a) the standard lower limit of the 95% confidence interval was below 1.0 -- and, therefore, results were not statistically significant -- for the entire twelve-year period except for a brief period just before the EPA issued the EPA Risk Assessment; and (b) even using a less rigorous 90% confidence interval, the lower limit was below 1.0 for much of the period.



Q: Did OSHA then issue a proposed rule regulating workplace smoking?

A: Yes, it issued a proposed rule in April 1994. JD-023473 is a copy of OSHA's proposed workplace smoking rule.

Q: Did Reynolds submit comments regarding OSHA's proposed rule regulating workplace smoking?

A: Yes, it did. JD-023989 is a copy of Reynolds' August 13, 1994 written comments.

Q: Did OSHA hold public hearings regarding its proposed workplace smoking rule?

A: Yes, it did.

Q: Did Reynolds participate in those hearing?

A: Yes, several Reynolds scientists testified at those hearings. I was among the Reynolds scientists who testified and discussed, among other things, research showing that home and workplace ETS exposures are different and, therefore, spousal smoking studies are not directly relevant when addressing the issue of workplace exposure. Reynolds also submitted post-hearing comments and a post-hearing brief, copies of which are, respectively, JD-023786 and JD-023787.

Q: Did you agree with the comments and testimony Reynolds submitted and provided to OSHA?

A: Yes, I did.

Q: Was that your genuinely-held belief?

A: Yes.

Q: Did Reynolds intend to influence OSHA's regulatory decision-making regarding the proposed workplace smoking rule?

A: Yes, it did.

Q: Has OSHA issued a final workplace smoking rule?

A: No. OSHA withdrew its proposed workplace smoking rule in 2001, and JD-003074 is a copy of the *Federal Register* notice of that withdrawal. The notice states in part that "OSHA is withdrawing its Indoor Air Quality proposal and terminating the rulemaking proceeding. In the years since the proposal was issued, a great many state and local governments and private employers have taken action to curtail smoking in public areas and in workplaces."

Q: Thank you, Dr. Ogden.